Pending Claims and Amendments

Claims 5, 6, 53-58, 71-74, 94-122, are currently pending in this application.

Claim Rejections – 35 USC § 102

Rejections Based on Testermann

Claims 5, 6, 53-55, 57-58, 71-74, 94-96, and 97-122 stand rejected under 35 U.S.C. 102(b) as being anticipated by Testerman et al. (US 5,522,862). Examiner states:

> Testerman et al. discloses a typical respiratory effort waveform for two complete respiratory cycles in Figure 2a. "Each wave of the waveform is characterized by a negative peak 30 on completion of expiration, a positive peak 35 on completion of inspiration and a turning point 40 which indicates the onset of inspiration. Each wave of the waveform can therefore be separated into a period of respiratory pause 32, an inspiratory phase 33 and an expiratory phase 34" (col.5, lines 25-31). Therefore, sensing the respiratory waveform implicitly corresponds to the patient's inspiration rate and the exhalation rate.
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> Testerman et al further discloses "a method for treating sleep apnea by bursts of electrical stimulation in response to sensed inspiration which includes detecting an arousal event and thereafter maintaining stimulation intensity in response to sensed inspiration below that which is perceptible to the patient. This level of stimulation is maintained for a predetermined period of time after detection of the arousal event in order to allow the patient to return to sleep without perceptible upper airway stimulation" (col. 2, lines 48-57)
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> As to claims 5-6, 57-58, 71-74, 98-105, 115 and 120, "a block diagram of the device includes a transmitter/controller 55, which is capable of sensing the inspiratory phase and transmitting an electrical stimulus pulse to muscles of the upper airway. The transmitter/controller 55 could be either an implantable or an external device but the following description will relate primarily to a battery powered external device. A respiratory transducer 60 such as a conventional belt transducer sends respiratory waveform information to the transmitter/controller 55 which sends stimulus pulses through an antenna/electrode system 65 to stimulate the muscles of the patient" (col. 6, lines 3-15). By sensing the stimulation waveform and then stimulating the respiratory muscles accordingly, Testerman et al. modifies the respiratory waveform and thus the inspiration rate and the exhalation rate.
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> As to Claims 53-55 and 94-96, "the microprocessor 75 identifies the inspiration phase of the waveform so that the system can supply a shaped stimulus burst for the duration of that phase at the antenna output 100. The microprocessor 75 is coupled to a dual digital/analog converter 105, which is also coupled at its

output to analog circuitry, which acts as a stimulus shaper 110. These elements work in combination to provide a shaped "stimulus window" which controls when stimulation will be provided and how much stimulation will be provided at the antenna output 100. The RF coupled stimulus burst is provided within this window. The microprocessor 75 sets the digital values for the digital/analog converter 105. The dual digital/analog converter 105 is connected in a cascaded arrangement with a first digital/analog section setting the amplitude of the stimulus pulse (i.e. from 0 to 8 volts in 256 increments of 32 millivolts) and the second digital/analog section setting the shape of the stimulus burst (i.e. the shape and duration of the stimulus during a rise time interval and a fall time interval as functions having 0-100% of full amplitude with eight bit resolution(1/256) for each 31 millisecond interval of output-typically, a linear ramping function of 250 millisecond for fall time is the default setting, or, to turn the stimulus on more quickly, a nonlinear ramping function, such as a sine function, could be used)" (col. 6, lines 13-28).

As to claims 108-111 and 116, "T1-T4 are monitored by the microprocessor 75. T1 is a measure of inspiratory rise time and is a sub-component of the active phase of inspiration. It represents the inspiratory rise time to a nominal 75% of peak value. T2 is the active inspiratory phase time. T3 is the active inspiratory/expiratory phase time. T4 is the length of a single respiratory cycle. In order to monitor these values, the microprocessor 75 needs to find the inspiratory turn point 242, the inspiratory peak PK1, the negative expiratory peak PK2, and the next inspiratory turn point 242a. In general, these points are found by various slope and/or amplitude criterion. Also monitored by the microprocessor are the PK1 and PK2 amplitude values for each phase. Average values of these variables may be computed and stored in the memory of the apnea treatment device in order to allow any method used to analyze the respiratory waveform or any method used to detect the onset of an apnea to adapt to normal variations in the waveform that may occur during sleep" (col 9-10, lines 57-67 and 1-7). The examiner further considers the inspiration time to be the same as this inspiration duration.

As to claim 109 and 117, "FIG. 4a shows that in a normal respiratory effort waveform 43, the inspiratory peaks 45 a-d are of approximately the same amplitude. By comparison, in Fig 4b, in a waveform 47 the inspiratory peaks 50a-d become significantly greater in amplitude at the onset of obstructive apnea than the immediately preceding inspiratory peak 52. This is reflective of the increased inspiratory effort undertaken by the patient in response to the difficulty of breathing through the obstructed airway" (col. 5, lines 48-56). Since Testerman et al. treats apnea, the increase inspiratory effort to increase in inspiratory peak amplitude as a result of apnea is reduced. Thus, Testerman et al. modifies the inspiration amplitude.

As to claims 113-114, "during a first period indicated as 53a, stimulation is enable producing a normal respiratory airflow" (col. 5, lines 64-66) Therefore, Testerman et al. treats apnea by returning the patient's respiration to normal respiratory and thus, to a predetermined waveform.

As to claims 106-107, 118-119 and 121-122, modification of the inhalation and exhalation rate will inherently affect the levels of oxygen and carbon dioxide in the patient's blood, since respiration directly affects blood gas equilibrium.

Rejections Based on Testerman or Testerman in view of Geddes

Claims 56 and 97 stand rejected under 35 U.S.C. 102(b) as being anticipated by Testerman et al or, in the alternative as being obvious over Testerman et al in view of U.S. Patent No. 4,827,935 to Geddes. Examiner states:

> Testerman et al. discloses the adjustment of several parameters, such as frequency, pulse duration, and therefore it is capable of being adjusted to control tidal volume.
>
> In the alternative, Testerman et al. discloses the claimed invention except for the tidal volume. Geddes et al. teaches that it is known to modify tidal volume as set forth in column 7, lines 28-32, with increased stimulation to increase tidal volume. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the stimulation treatment as taught by Testerman et al. with the stimulation to modify the tidal volume as taught by Geddes et al. in order to increase the volume of air inspired to assist in the respiration of the patient.

Testerman et al.

Testerman et al. describe a system for treating sleep apnea that stimulates muscles associated with the upper air passageway to open the airway. Testerman in theory creates patency of the airway (see col.2 line 67-col. 13, line1) which may allow further air flow through the lungs if and only if there is innate respiration present. (See col. 2, line 48-54). Stimulation does not elicit a diaphragm respiratory response as it is applied to the upper airway and not to tissue whereby a diaphragm response may be elicited. Testerman does not cause respiration. Testerman does not stimulate tissue to elicit a diaphragm respiratory response to cause or control breathing. Any diaphragm respiration present when using the Testerman device is not controlled by stimulation but rather is innate breathing controlled by the central respiratory drive.

The present invention provides stimulation that directly affects the diaphragm to control the respiration waveform.

Claims 5, 6, 53-58, 94-122

Claims 5, 6, 53-58, 94-122 provide at least one electrode configured to deliver electrical stimulation to tissue to thereby elicit a diaphragm respiratory response. As set forth above, Testerman does not provide stimulation that elicits a diaphragm respiratory response.

Claims 71-74

Claims 71-74 recite a method that includes sensing a characteristic of respiration, comparing it to a desired characteristic and then electrically stimulating tissue to alter respiration to cause a characteristic to approach the desired characteristic. Thus, the method as claimed includes a proportional control whereby after a comparison of a characteristic to a desired characteristic stimulation is provided that causes the characteristic to approach the value of the desired characteristic. Testerman does not disclose this proportional control of stimulation to cause a respiration characteristic to approach a desired characteristic.

Accordingly Applicant submits that the claimed invention is not anticipated by Testerman. Applicants further submit that the invention is not obvious over Testerman in View of Geddes and further that the combination of the references would not result in the claimed invention.

Conclusion

Applicant accordingly submits that claims 5, 6, 53-58, 71-74, 94-122 are patentable over the prior art relied on by Examiner and thus are in condition for allowance. An early and favorable action on the merits is respectfully requested.

Respectfully Submitted,

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